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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,482	02/28/2002	Bertha K. Madras	56595/70207)	5723

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EXAMINER
SOLOLA, TAOFIQ A

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 01/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,482	MADRAS ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims1-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The term "DAT" on the last line of claim 1, and in claims 2-3, 16, 18, 20, 24, is not defined in the specification on the first occurrence in accordance with standard scientific practice. Therefore, the specification fails to provide adequate support for claims 1-25. By defining the term the rejection would be overcome. However, applicant should note that the introduction of new subject matter into the specification would raise the issue of new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "DAT" on the last line of claim 1, and in claims 2-3, 16, 18, 20, 24, is not defined in the claims so as to ascertain the metes and bounds of claims 1-25. Therefore, claims 1-25 are indefinite. A claim must stand alone to define the inventions, and incorporation into

the claims by reference to the specification or an external source is not permitted. Ex parte Fressola, 27 USPQ 2d 1608, BdPatApp & Inter. (1993). See the Examiner's suggestion above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meltzer et al., WO 99/02526.

Applicant claims compounds of formulae I, II and III, their composition and method of use as inhibitors of serotonin (5-hydroxytryptamine) reuptake of monoamine transporter. Applicant claims the compounds as having specific SERT/DAT selectivity ratios.

Determination of the scope and content of the prior art (MPEP §2141.01)

Meltzer et al., teach compounds of formulae I, II and III, their composition and method of use as inhibitors of 5-hydroxytryptamine (serotonin) reuptake of monoamine transporter. See pages 7-25, and the examples. Meltzer et al., also teach selectivity of the compounds for DAT and SERT, and that certain members of the compounds have higher selectivity for DAT than SERT.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Meltzer et al., is that applicant is claiming specific SERT/DAT selectivity ratios.

Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)

However, specific SERT/DAT selectivity ratio is a further characterization of the compounds, and does not render the compounds novel or inventive. Determination of the specific SERT/DAT selectivity ratio is not in and of itself patentable over the prior art of Meltzer et al., because it is not patentable significant.

Therefore, the instant invention is prima facie obvious from the teaching of Meltzer et al. Having known that the compounds have different selectivity for DAT and SERT, one of ordinary skill in the art would have known a routine procedure to determine the values of the selectivity ratios. The motivation is from the teaching of Meltzer et al., that the compounds have different selectivity for DAT and SERT.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 5,948,933. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the instant case, applicant claims compounds of formulae I, II and III, their composition and method of use as inhibitors of serotonin (5-hydroxytryptamine) reuptake of monoamine transporter. Applicant claims the compounds as having specific SERT/DAT

selectivity ratios. In US "933, applicant claims compounds of formulae I, II and III, their composition and method of use as inhibitors of 5-hydroxytryptamine reuptake of monoamine transporter.

The difference between the instant invention and that of US '933 is that applicant is claiming specific SERT/DAT selectivity ratios. However, specific SERT/DAT selectivity ratio is a further characterization of the compounds, and does not render the compounds novel or inventive. Determination of the specific SERT/DAT selectivity ratio is not in and of itself patentable significant.

Therefore, the instant claims are prima facie obvious from the claims of US '933. Having known that the compounds have different selectivity for DAT and SERT, one of ordinary skill in the art would have known a routine procedure to determine the values of the selectivity ratios.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Taofiq A. Solola whose telephone number is (703) 308-4690. The examiner is on flexible work schedule and is generally out of the office on Wednesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

January 21, 2003